



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/527,904

07/07/2005

Robert R Redfield

014835-77.00-015

9067

24239 7590 03/18/2009

MOORE & VAN ALLEN PLLC

P.O. BOX 13706

Research Triangle Park, NC 27709

EXAMINER

CARTER, KENDRA D

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

03/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/527,904 | Applicant(s) REDFIELD ET AL. | |
| | Examiner KENDRA D. CARTER | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Group I, claims 1-10, are drawn to a pharmaceutical composition for increasing concentrations of chemokines comprising at least one G1 phase arresting compound.

II. Group II, claims 11-17, drawn to a method for inducing increased levels of anti-HIV beta-chemokines in activated lymphocytes comprising administering a composition comprising at least one G1 phase arresting agent.

III. Group III, claims 18-26, are drawn to a method for modifying synthesis of receptor ligand to alter extracellular recognition of a receptor by an infections agent comprising administering to a cell at least one G1 phase arresting agent.

Art Unit: 1617

IV. Group IV, claims 27-36, are drawn to a method of combating a virus infection comprising administering a G1 phase arresting compound.

V. Group V, claims 37-42, drawn to a method of maintaining viral control of an HIV infection comprising administering at least one antiviral agent in combination with at least one G1 phase arresting compound.

VI. Group VI, claims 43-47, are drawn to a method to inhibit replication of HIV in a HIV infected subject comprising, a) administering at least one G1 phase arresting agent for a first predetermined time period, and b) administering the G1 phase agent with at least one antiviral agent for a second predetermined time period, wherein the first and second time periods are sequential in a cyclic schedule.

VII. Group VII, claims 48-50, are drawn to a method of preventing HIV infection in a subject potentially exposed to HIV comprising administering at least one G1 phase arresting compound.

VIII. Group VIII, claims 51-54, are drawn to a method to reduce an effective dosage of an HIV antiviral agent comprising substituting the antiviral agent with a G1 phase arresting compound; augmenting the antiviral agent with a G1 phase arresting compound; or substituting a portion of the antiviral agent with a G1 phase arresting compound.

The inventions listed as Groups I to VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Particularly, the special technical feature is a G1 phase arresting compound. Long et al. (Cancer Research, August 15, 1994, vol. 54, pp. 4355-4361) teach paclitaxel, which inhibits progression of mitotic cells to G1 phase. Thus, the special technical feature is taught in the prior art.

Species Restriction

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- I. G1 phase arresting compound in claims 1, 3, 11, 12, 18, 23, 27, 31, 37, 39, 43, 44, 47, 48, 49, 51, 52 (for example an election would be one specific compound such as sodium butyrate)
- II. antiviral agent in claims 2, 4-6, 13-16, 22, 24-25, 31-33, 37, 45, 46, 47, 51, 53 and 54 (for example an election would be a one specific agent such as stavudine)
- III. receptor ligand in claims 18-20 (for example an election would be one specific receptor ligand)

IV. chemokine receptor in claims 27 and 28 (for example an election would be one specific chemokine receptor such as CCR5)

Applicant is required, in reply to this action, to elect a single species, not a sub-genus, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. Particularly, the special technical feature in Group I does is not the same in any of the other Groups II through IV. In other words, the special technical feature in Group II (antiviral agent) is not present in Group I (G1 phase arresting compound).

A telephone call was not made to the Applicant due to the complexity of the restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kendra D Carter/
Examiner, Art Unit 1617

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617